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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 10/592,973 | 11/07/2006 | David Louis Feldman | 33687-US-PCT | 3773 |
| 1095 | 7590 | 12/02/2009 | EXAMINER | |
| NOVARTIS | | | FINN, MEGHAN R | |
| CORPORATE INTELLECTUAL PROPERTY | | | ART UNIT | PAPER NUMBER |
| ONE HEALTH PLAZA 104/3 | | | | 1614 |
| EAST HANOVER, NJ 07936-1080 | | | | |
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| | | 12/02/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/592,973 | FELDMAN ET AL. | |
| | Examiner | Art Unit | |
| | MEGHAN FINN | 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 August 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) 2 and 4-10 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,11 and 12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8/19/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's Amendment filed August 19, 2009 has been received and entered into present application. No claims were canceled and claims 11-12 were added by applicant. Claims 2, and 4-10 remain withdrawn and thus claims 1, 3, 11 and 12 are pending.

Applicants' arguments, filed August 19, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Applicant submitted an information disclosure statement (IDS) on August 19, 2009. This reference was identical to the one previously considered that was mailed November 7, 2006. This time applicant provided copies of the foreign and non-patent literature references. The US patent applicants were marked not considered on the IDS submitted August 19, 2009 because they have already been considered, however the rest of the references were considered. All references submitted by applicant have been considered once.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (US 2003/0114389 A1, cited on applicant's IDS), which is already of record in the office action mailed June 09, 2009 of which reasons are herein incorporated by reference.

Previously, claims 1 and 3 were rejected over Webb et al., applicant has added claim 12, which claims that the diabetes of claim 1 is not associated with hypertension. As discussed previously, Webb et al. teaches a composition comprising a renin inhibitor of formula I (page 1, [0001]) which is the same compound claimed, and they teach use of that compound for treatment of type 2 diabetes (page 3, [0031] and page 4, [0046]). They do not mention hypertension, however since claim 12 is directed to patients without hypertension the method of Webb et al. reads upon those patients. Applicant has argued that Webb et al. does not teach a monotherapy for the compound of formula I and instead teaches a combination therapy with an insulin secretion enhancer and insulin sensitizer. However, the Examiner respectfully reminds Applicant that the claims are not limited to a monotherapy. Applicant has claimed a method of treatment

"comprising administration" which is open to other compounds or therapies. Thus the claims read upon the combination therapy of Webb et al. Applicant's arguments were very carefully considered but not deemed persuasive and thus the rejection of claims 1 and 3 is maintained. A new rejection of claim 12 is necessitated by its addition to the claims.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection, necessitated by amendment to claims)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (US 2003/0114389 A1, cited on applicant's IDS), in view Bridon et al. (US 6,849,714)

in further view of Kirpichnikov (Current Diabetes Report, 2002, Vol. 2, No. 3, pages 251-257), each already of record, for the reasons set forth at page 7 of previous office action dated June 09, 2009, of which reasons are herein incorporated by reference.

In the previous office action claims 1 and 3 were rejected over Webb et al. in view of Bridon et al. and Kirpichnikov et al. Previously, it was not clear if the patients of claims 1 and 3 required to have hypertension or not, applicant has amended the claims such that only the newly added claim 11 requires the diabetes to be associated with hypertension. As discussed previously, Webb et al. teaches the same drug for treatment of diabetes. Bridon et al. teaches that renin inhibitors are known to treat hypertension and Kirpichnikov et al. teaches that over 70% of diabetic patients have hypertension. Thus it would have been obvious to use the method of Webb et al. to treat diabetic patients with hypertension. Applicant's only arguments against the previous rejection were the same as above, that Webb et al. does not teach a monotherapy. As discussed above, applicant has not limited their claims to a monotherapy and the claims still read upon the combination therapy taught by Webb et al.

This is a new rejection necessitated by claim 11 addition to the claims.

Conclusion

Rejection of claims 1 and 3 is deemed proper and is maintained. The New rejection for claims 11 and 12 is necessitated by their addition to the claims.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614